IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	David E. Francischelli et al.	Examiner: Michael F. Peffley
Serial No.:	10/752,135	Group Art Unit: 3739
Filed:	January 6, 2004	Docket No.: M190.257.101/P-8922.06
Title:	SYSTEM FOR ASSESSING TRANSMURALITY OF ABLATION LESIONS	

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on May 16, 2008, appealing the final rejection of claims 1-12 and 16-29 of the above-identified application as set forth in the Final Office Action mailed February 12, 2008. The Appeal Brief is submitted in Response to a Notice of Panel Decision mailed on February 18, 2009

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of $540.00 for filing a Brief in Support of an Appeal as set forth under 37 C.F.R. § 41.20(b)(2). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 1-12 and 16-29.

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REAL PARTY IN INTEREST

The intellectual property embodied in the pending application is assigned to MEDTRONIC, INC.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present Appeal.

STATUS OF CLAIMS

In the Notice of Panel Decision mailed February 19, 2009 and a Final Office Action mailed February 12, 2008, claims 1-12 and 16-29 were finally rejected. Claims 13-15 were allowed. Claims 1-29 are pending in the application. Claims 1-12 and 16-29 are the subject of the present Appeal.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to final rejection mailed on February 12, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The Summary is set forth as an exemplary embodiment as the language corresponding to independent claims 1, 20, and 21. Discussions about elements of these claims can be found at least at the cited locations in the specification by their page and line numbers and drawings by their reference numerals.

Independent claim 1 is directed to a system for assessing transmurality of an ablation in a tissue (page 5, lines 8-9). The system includes an ablation apparatus 20 (page 7, lines 26-27; page 8, lines 8-11) operatively adapted to deliver ablation energy to a first side of the tissue (page 10, lines 6-7). A temperature-sensing pad 24 (page 7, line 29 through page 8, line 1) is operatively adapted to sense temperature along a second side of the tissue opposite the first side (page 10, lines 7-9) in response to ablation energy delivered to the first side. The temperature-sensing pad 24 comprises an array of temperature elements 34 (page 9, lines 9-13) in close proximity to each other to effectively detect continuous temperature along the

second side of the tissue (Figures 2-4, page 10, lines 26-27). A suction opening is operatively adapted to anchor the temperature-sensing pad to the tissue, and it is positioned along a tissue contact surface (page 10, line 29 to page 11, line 3). A suction source is in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening (page 19, lines 26-27). An output device is in communication with the pad, and the output device is operatively adapted to indicate continuous transmurality of the ablated tissue based on the sensed temperature (page 21, lines 11-29).

Independent claim 20 is directed to a system for ablating a tissue. The system includes an ablation apparatus (page 7, lines 26-27; page 8, lines 8-11) operatively adapted to ablate a first side of the tissue (page 10, lines 6-7). The ablation apparatus comprises at least one suction opening positioned along a tissue contact surface where the suction opening is operatively adapted to anchor the ablation apparatus to the tissue (page 21, line 25). The system also includes a temperature-sensing pad (page 7, line 29 through page 8, line 1) operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy being delivered to the first side (page 10, lines 7-9). The temperature-sensing pad comprises an array of temperature elements (page 9, lines 9-13) in close proximity to each other to effectively detect continuous temperature along the second side of the tissue (Figures 2-4, page 10, lines 26-27). At least one suction opening is positioned along a tissue contact surface, and the suction opening is operatively adapted to anchor the temperature-sensing pad to the tissue (page 10, line 29 to page 11, line 3). A suction source is in communication with the suction openings and provides suction to the suction openings (page 19, lines 26-27). An output device is in communication with the pad and adapted to provide a visual display of continuous transmurality of the ablated tissue based on the temperature sensed along the second side of the tissue (page 21, lines 11-29).

Independent claim 21 is directed to a system for assessing transmurality of a linear ablation lesion in a tissue. The system comprises an ablation apparatus (page 7, lines 26-27; page 8, lines 8-11) operatively adapted to deliver ablation energy to a first side of the tissue to create a linear ablation lesion (see Figures 2-4). An array of temperature sensors (page 7, line 29 through page 8, line 1) is operatively adapted to sense temperature at a plurality of points of contact along a second side of the tissue (Figures 2-4, page 10, lines 6-7) in response to ablation energy being delivered to the first side of the tissue. The second side of the tissue is

opposite the first side of the tissue. The temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue (Figures 2-4, page 10, lines 26-27). The system also includes an output device in communication with the array of temperature sensors, and the output device is operatively adapted to provide an indication of continuous transmurality of the linear ablation lesion at the second side of the tissue based on the sensed temperature (page 21, lines 11-29).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 21, 22, 25, and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Stern U.S. Patent No. 5,443,463, in view of the Taylor U.S. Patent No. 6,113,592.

II. Claims 1-4, 6-9, 12, 16 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stern in view of the Nagai et al. U.S. Patent No. 5,172,949 and Taylor.

III. Claims 5, 17, and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stern, Taylor and Nagai as applied to claims 1 and 4 above and further in view of the Chinn U.S. Patent No. 5,647,868.

IV. Claims 10 and 11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stern, Taylor and Nagai as applied to claim 1 above and further in view of the Hoffman U.S. Patent No. 4,682,605.

V. Claims 23, 24 and 26-28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Stern and Taylor in view of the Chinn.

VI. Claim 20 has yet to be examined.

ARGUMENT

I. The Applicable Law

With regard to a 35 U.S.C. § 103 obviousness rejection: "Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case." M.P.E.P. 2141 (emphasis in the original). The Examiner bears the burden under 35 U.S.C. § 103 in establishing a *prima*

facie case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 [5 USPQ2d 1596, 1598] (Fed. Cir. 1988).

One criteria that must be satisfied to establish a *prima facie* case of obviousness is the reference or combined references must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981 [180 USPQ 580] (C.C.P.A. 1974).

However, "[a] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.,* 127 S. Ct. 1727, 1731 [82 USPQ2d 1385, 1389] (2007). In making an obviousness determination over a combination of prior art references, it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id. at* 1738 [1396].

In order to facilitate review of the determination of whether there was an apparent reason to combine known elements in the fashion claimed by the patent at issue, the "analysis should be made explicit." *Id. at* 1738 [1396]. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (Fed. Cir. 2006) (cited with approval in *KSR*, 127 S. Ct. at 1738 [82 USPQ2d at 1396])

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 [227 USPQ 543, 551] (Fed. Cir. 1985). Furthermore, claims must be interpreted in light of the specification, claim language, other claims, and prosecution history. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 [1 USPQ2d 1593, 1597] (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). At the same time, a prior patent cited as a § 103 reference must be considered in its entirety, "*i.e.* as a *whole*, including portions that lead away from the invention." *Id.* That is, the Examiner must recognize and consider not only the similarities, but also the critical differences between the claimed invention and the prior art as one of the factual inquiries pertinent to any obviousness inquiry under 35 U.S.C. § 103. *In re Bond*, 910 F.2d 831, 834 [15 USPQ2d 1566, 1568] (Fed. Cir. 1990) (emphasis added).

Furthermore, the Examiner must avoid hindsight. *Id.* "A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR,* 127 S. Ct. at 1739 [82 USPQ2d at 1397] (citing to *Graham v. John Deere*, 383 U.S. 1 [148 USPQ 459] (1966) in warning against a temptation to read into the prior art the teachings of the invention at issue and instructing courts to guard against slipping into the use of hindsight).

"[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR,* 127 S. Ct. at 1737 [82 USPQ2d at 1395] (citing to *United States v. Adams*, 383 U.S. 39, 51-52 [148 USPQ 479] (1966).

In conclusion, an Appellant is entitled to a patent grant if a *prima facie* case of obviousness is not established. The Federal Circuit has endorsed this view in stating: "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the Appellant is entitled to grant of the patent." In re Oetiker, 977 F.2d 1443, 1446 [24 USPQ2d 1443, 1448] (Fed. Cir. 1992).

II. Rejection of Claims 21, 22, 25, and 29 under 35 U.S.C. §103(a) as being unpatentable over the Stern U.S. Patent No. 5,443,463, in view of the Taylor U.S. Patent No. 6,113,592.

Claims 21, 22, 25, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teachings of Taylor. Claim 21 is independent, and claims 22-29 depend from claim 21. Appellants submit that independent claim 21 is patentably distinguishable over the rejection because the claim includes features not taught or made obvious in any proposed combination of Stern and Taylor. Appellants also submit that claims 22, 25, and 29 are also patentably distinguishable over the rejection by virtue of their dependency from claim 21.

A. Stern Does Not Teach or Make Obvious Features of Claim 21

Appellants dispute the statements in the Final Office Action the primary reference of Stern teaches or makes obvious the features of independent claim 21. For example, Appellants dispute that Stern teaches or makes obvious the claimed features of "an array of

temperature sensors operatively adapted to sense temperature at a plurality of points of contact along a second side of the tissue in response to ablation energy being delivered to the first side of the tissue, . . . , wherein *the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue*" (emphasis supplied).

Stern teaches a coagulating forceps for selectively coagulating blood vessels or tissue containing blood vessels with an energized radio-frequency power. The forceps include a plurality of electrodes on one jaw and a plurality of temperature sensors on the other jaw. (Stern, column 3, lines 62-64). The forceps are clamped across a vessel as shown in Fig. 1B of Stern, and the tissue is heated for a predetermined period in order to ensure the coagulation of the vessel. (Stern, column 4, lines 23-26.) The temperature sensors are employed to sense the tissue temperature. Allowing the tissue temperature to reach a desired value and maintaining that temperature at that level for an appropriate period of time provides feedback concerning coagulation. (Stern, column 6, lines 16-20.)

The Final Office Action sets forth that Stern teaches, "an array of temperature sensors are in close proximity are provided . . . to sense temperature of the opposite side of the tissue." The Final Office Action further states "in as much as applicant's specification teaches that temperature provides an indication of lesion transmurality, the examiner maintains that the Stern et al system in inherently adapted to provide an indication of transmurality of the lesion (i.e., coagulation zone) since it is monitoring tissue temperatures."

Even if, as set forth in the final Office Action that the Stern et al system in inherently adapted to provide an indication of transmurality of the lesion, these features are not enough to meet the terms of the claims. Stern teaches a system that provides for a determination of coagulation through plurality of spaced-apart sensors each corresponding with an electrode on the other side of blood vessel or a tissue. (*See*, Stern Figs. 1, 2, and 3, column 5, lines 21-22.) Stern Figures 1B, 2A, 2B, 2C, and 6 show the spaced-apart nature of the electrode-sensor pairs. The electrode-sensor pairs are used to direct specific energy to selected electrodes depending on the coagulation (Stern, column 6, lines 36-40.) The teachings of Stern are directed to monitoring the temperature of tissue proximate the electrode, rather than the spaces between the electrodes. The temperatures in the spaces in between the electrodes are unknown, but are assumed to provide for coagulation through the "slow cook" treatment.

(See, Stern, column 6, lines 24-29). Thus, the spaced-apart electrode-sensor pairs of Stern do not "*effectively detect continuous temperature along the second side of the tissue*" as required in the claim.

The prior art does not make obvious a modification to the spaced-apart configuration of Stern to detect continuous temperature along the second side of the tissue. Stern provides for temperature sensors to provide feedback on the corresponding electrode for control purposes. (*See* Stern, column 6, lines 36-40.) This configuration of detecting the individual performance of the sensors is inapposite a configuration for determining continuous temperature, where the heating of a particular sensor is immaterial.

B. Taylor Also Does Not Teach or Make Obvious Features of the Claim 21

The Final Office Action states Stern fails "to specifically disclose that the output device provides for continuous indication of lesion transmurality." For this, the Final Office Action cites the secondary reference of Taylor as disclosing "another apparatus for performing transmural lesions, and specifically disclos[ing] using temperature monitoring to inform the user of the progress of the lesion. In particular, Taylor discloses a computer having a display for continuously showing the temperature progress as an indication of lesion transmurality." Appellants dispute this conclusion and submit that Taylor does not teach or make obvious the features of claim 21 including "the output device operatively adapted to provide [1] *an indication of continuous transmurality* of [2] *the linear ablation lesion* at the second side of the tissue based on the sensed temperature" (emphasis supplied).

Taylor teaches a device that performs tissue ablation but avoids the disadvantages of inaccurate temperature measurements at the ablation site, which has led to unnecessary injury. (*See* Taylor, column 6, lines 32-38.) The device provides an indication of a current through a galvanic cell formed through the body with an ablation electrode at a tissue site. (*See* Taylor, column 7, lines 56-61). When constant power is applied to the electrode to the ablation site, the measured current rises until ablation occurs, at which point the current peaks and begins to decrease. (*See* Taylor, column 11, lines 9-29). After ablation occurs, power can be reduced or terminated to avoid unnecessary damage to the tissue.

Although Taylor teaches using a combination of electrical power, temperature, and current measurements to detect when ablation begins to occur in tissue, there is no teaching

of "*an indication of . . . transmurality*" and thus "*an indication of continuous transmurality*" as set forth in the claim. Taylor does not address the issue of transmurality, and the only related teaching in Taylor is, "it is believed that the depth of ablation can be controlled as a function of power level and time subsequent to occurrence of ablation." (Taylor, column 12, lines 17-19.) Taylor inherently states that it does not provide a solution to the problem of determining transmurality in ablated tissue, and thus cannot be used for a teaching or suggestion of an "output device operatively adapted to provide an *indication of continuous transmurality* of the linear ablation lesion at the second side of the tissue based on the sensed temperature" (emphasis supplied) as set forth in claim 21.

Furthermore, the claim is directed to a "linear ablation lesion" as indicated in the feature of claim 21 where "the output device operatively adapted to provide an indication of continuous transmurality of the *linear ablation lesion* at the second side of the tissue based on the sensed temperature" (emphasis supplied). Taylor provides a system to provide an indication of when discrete ablation has occurred not the "linear ablation" of the claim. For example, discrete ablation, such as in Taylor, is discussed in the specification as ablating "discrete positions along the tissue . . . for example when ablating accessory pathways, such as in Wolff-Parkinson-White syndrome or AV nodal reentrant tachycardias" at page 2, lines 9-10. Such ablation is effective even when not transmural.

On the other hand, the claimed "linear ablation" is used in cases of atrial fibrillation, where the aim is to reduce the total mass of contiguous (electrically connected) atrial tissue below a threshold believed to be critical for sustaining multiple reentrant wavelets." (Specification at page 2, lines 12-14). There is no indication in Taylor that a device for detecting discrete ablation could be suitable for linear ablation. Rather, one skilled in the art would not be inclined to use the teachings of Taylor because it detects only ablation and would not provide a suitable output to determine continuous linear ablation, or "an indication of continuous transmurality of the linear ablation lesion" as required in the claim. Simply providing of output that an ablation has occurred as in Taylor is vastly inadequate to a determination that "continuous transmurality of linear ablation," as required in the claim, has occurred. Accordingly the teachings of Taylor do not meet or make obvious the cited features of claim 21.

C. Claim 21 is Patentably Distinguishable Over Stern In View of Taylor

Claim 21 is patentably distinguishable over the combination of the teachings of Stern in view of the teachings of Taylor. As set forth above, Stern does not teach, and the prior art does not make obvious, the claimed features of "temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." These features are also not found in Taylor because Taylor does not take temperature measurements in this manner. Additionally, Appellants agree with the statement in the Final Office Action that Stern fails "to specifically disclose that the output device provides for continuous indication of lesion transmurality." As described above, Taylor does not teach, and the prior art does not make obvious, the claimed features of an "output device operatively adapted to provide an indication of continuous transmurality of the linear ablation lesion at the second side of the tissue based on the sensed temperature." Because these features are missing from the prior art of record, the features cannot be found in any proposed combination of the references. Accordingly, Appellants submit that claim 21 is patentably distinguishable from the combination of Stern and Taylor and request that the rejection be reversed.

D. Claims 22, 25, and 29 are Patentably Distinguishable Over Stern In View of Taylor

Each of claims 22, 25, and 29 depend directly from independent claim 21, which has been shown above to be patentable. Dependent claims 22, 25, and 29 serve to further define claim 21. By virtue of their dependency to claim 21, claims 22, 25, and 29 are also patentably distinguishable from the combination of Stern and Taylor and request that the rejection be reversed.

III. Rejection of Claims 1-4, 6-9, 12, 16 and 19 under 35 U.S.C. §103(a) as being unpatentable over Stern in view of the Nagai et al. U.S. Patent No. 5,172,949 and Taylor.

Claims 1-4, 6-9, 12, 16, and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teachings of Nagai and Taylor. Claim 1 is independent, and claims 2-4, 6-9, 12, 16, and 19 depend from claim 1. Appellants submit that independent claim 1 is patentably distinguishable over the rejection because the claim includes features not taught or made obvious in any proposed combination of Stern, Nagai,

and Taylor. Appellants also submit that claims 2-4, 6-9, 12, 16, and 19 are also patentably distinguishable over the rejection by virtue of their dependency from claim 1.

Claim 1 includes features previously discussed with relation to independent claim 21 above. For example, claim 1 includes the features of "the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." Claim 1 further includes the features of an "output device operatively adapted to indicate continuous transmurality of the ablated tissue based on the sensed temperature." As discussed above in relation to claim 21, these features are not taught by either Stern or Taylor, or made obvious by the prior art. Accordingly, these features of claim 1 are not taught by either Stern or Taylor, or made obvious by the prior art.

Nagai is not cited to teach or make obvious these features. Rather, Nagai is cited in the Final Office Action to disclose that "it is known to provide a combination suction and temperature sensing element to hold a working surface in contact with a device for monitoring temperature" as set forth on page 3 of the Final Office Action.

Stern, Nagai, and Taylor do not teach, and the prior art does not make obvious, the claimed features of "temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue." As described above, Stern, Nagai, and Taylor do not teach, and the prior art does not make obvious, the claimed features of an "output device operatively adapted to indicate continuous transmurality of the ablated tissue based on the sensed temperature." Because these features are missing from the prior art of record, the features cannot be found in any proposed combination of the references. Accordingly, Appellants submit that claim 1 is patentably distinguishable from the combination of Stern, Nagai, and Taylor and request that the rejection be reversed.

Claims 2-4, 6-9, 12, 16 and 19 depend from independent claim 1, which has been shown above to be patentable. Dependent claims 2-4, 6-9, 12, 16 and 19 serve to further define claim 1. By virtue of their dependency to claim 1, claims 2-4, 6-9, 12, 16 and 19 are also patentably distinguishable from the combination of Stern, Nagai, and Taylor and request that the rejection be reversed.

IV. Rejection of Claims 5, 17, and 18 under 35 U.S.C. §103(a) as being unpatentable over Stern, Taylor and Nagai as applied to claims 1 and 4 above and further in view of the Chinn U.S. Patent No. 5,647,868.

Dependent claims 5, 17, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teachings of Taylor, and Nagai as applied to claims 1 and 4 above, and further in view of Chinn. Appellants submit that claims 5, 17, and 18 are patentably distinguishable over the rejection because the claim includes features not taught or made obvious in any proposed combination of Stern, Taylor, Nagai, and Chinn.

Claims 5, 17, and 18 depend from independent claim 1, which has been shown above to be patentable over any proposed combination of Stern, Taylor, and Nagai. As described above, Stern, Taylor, and Nagai do not teach, and the prior art does not make obvious, features of independent claim 1. Chinn is not cited to teach, and it does not include, the missing features of independent claim 1, either. Rather, Chinn is cited in the Final Office Action to teach an "RF treatment system that uses temperature sensing to control RF output." There is no teaching in Chinn, and the prior art does not make obvious, the features missing in independent claim 1. Because these features are missing from each of the references of Stern, Taylor, Nagai, and Chin separately, they must be missing from any proposed combination of the references in claim 1 or its dependent claims. Accordingly, Appellants request removal of the rejection of claims 5, 17, and 18.

V. Rejection of Claims 10 and 11 under 35 U.S.C. §103(a) as being unpatentable over Stern, Taylor and Nagai as applied to claim 1 above and further in view of the Hoffman U.S. Patent No. 4,682,605.

Dependent claims 10 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teachings of Taylor, and Nagai as applied to claim 1 above, and further in view of Hoffman. Appellants submit that claims 10 and 11 are patentably distinguishable over the rejection because the claim includes features not taught or made obvious in any proposed combination of Stern, Taylor, Nagai, and Hoffman.

Claims 10 and 11 depend from independent claim 1, which has been shown above to be patentable over any proposed combination of Stern, Taylor, and Nagai. As described above, Stern, Taylor, and Nagai do not teach, and the prior art does not make obvious,

features of independent claim 1. Hoffman is not cited to teach, and it does not include, the missing features of independent claim 1, either. Rather, Hoffman is cited in the Final Office Action to teach "that it is old and well-known to use temperature sensing devices such as liquid crystals and temperature sensing chemicals to provide detailed temperature mapping of tissue." There is no teaching in Hoffman, and the prior art does not make obvious, the features missing in independent claim 1. Because these features are missing from each of the references of Stern, Taylor, Nagai, and Hoffman separately, they must be missing from any proposed combination of the references in claim 1 or its dependent claims. Accordingly, Appellants request removal of the rejection of claims 10 and 11.

VI. Rejection of Claims 23, 24 and 26-28 under 35 U.S.C. §103(a) as being unpatentable over Stern and Taylor in view of the Chinn.

Dependent claims 23, 24, and 26-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stern in view of the teachings of Taylor, and in view of the teachings of Chinn. Appellants submit that claims 23, 24, and 26-28 are patentably distinguishable over the rejection because the claim includes features not taught or made obvious in any proposed combination of Stern, Taylor, and Chinn.

Claims 23, 24, and 26-28 depend from independent claim 21, which has been shown above to be patentable over any proposed combination of Stern and Taylor. As described above, Stern and Taylor do not teach, and the prior art does not make obvious, features of independent claim 21. Chinn is not cited to teach, and it does not include, the missing features of independent claim 21, either. Rather, Chinn is cited in the Final Office Action to teach an "RF treatment system that uses temperature sensing to control RF output." There is no teaching in Chinn, and the prior art does not make obvious, the features missing in independent claim 21. Because these features are missing from each of the references of Stern, Taylor, and Chin separately, they must be missing from any proposed combination of the references in claim 21 or its dependent claims. Accordingly, Appellants request removal of the rejection of claims 23, 24, and 26-28.

VII. Claim 20

Independent claim 20 was added in an amendment dated January 23, 2006, but no Office Action since that time has specifically addressed the claim or has otherwise indicated the claim has been examined. Appellants had amended claim 20 and requested examination of the claim in an Amendment and Response submitted on December 18, 2007. Appellants submit that the features of independent claim 20 are patentably distinguishable over the prior art references of record.

CLAIMS APPENDIX

1. A system for assessing transmurality of an ablation in a tissue comprising:

an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue;

a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side, the temperature-sensing pad comprising an array of temperature elements in close proximity to each other to effectively detect continuous temperature along the second side of the tissue, and at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;

a suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening; and

an output device in communication with the pad, the output device operatively adapted to indicate continuous transmurality of the ablated tissue based on the sensed temperature.

2. The system of claim 1 wherein the pad comprises temperature-sensing elements incorporated therein.

3. The system of claim 1 wherein the transmurality of the ablated tissue indicated by the output device is a function of the temperature sensed along the second side of the tissue.

4. The system of claim 2 wherein the temperature-sensing elements are arranged in a grid pattern.

5. The system of claim 4 wherein the output device displays a representation of the grid pattern to indicate where the ablation is both transmural and continuous.

6. The system of claim 1 wherein the output device includes a processor for processing a signal received from the temperature-sensing pad.

7. The system of claim 1 wherein the output device includes an amplifier for amplifying a signal received from the temperature-sensing pad.

8. The system of claim 2 wherein the temperature-sensing elements are thermocouples.

9. The system of claim 2 wherein the temperature-sensing elements are thermisters.

10. The system of claim 2 wherein the temperature-sensing elements are temperature-sensing liquid crystals.

11. The system of claim 2 wherein the temperature-sensing elements are temperature-sensing chemicals.

12. The system of claim 2 wherein the temperature-sensing elements are operatively adapted to be located within the tissue.

13. A system for assessing transmurality of an ablation in a tissue comprising:

an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue;

a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side, wherein the pad is mounted on a glove, the temperature-sensing pad comprising at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;

a suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening; and

an output device in communication with the pad, the output device operatively adapted to indicate continuous transmurality of the ablated tissue.

14. A system for assessing transmurality of an ablation in a tissue comprising:

an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue;

a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side, wherein the pad is formed as a portion of a glove, the temperature-sensing pad comprising at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;

a suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening; and

an output device in communication with the pad, the output device operatively adapted to indicate continuous transmurality of the ablated tissue.

15. A system for assessing transmurality of an ablation in a tissue comprising:

an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue;

a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side, wherein the pad is operatively adapted to be fitted over a finger, the temperature-sensing pad comprising at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;

a suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening; and

an output device in communication with the pad, the output device operatively adapted to indicate continuous transmurality of the ablated tissue.

16. The system of claim 1 wherein the pad further comprises a conductive element incorporated therein.

17. The system of claim 1 wherein the output device comprises a visual display on a monitor.

18. The system of claim 1 wherein the output device comprises a visual display on the pad.

19. The system of claim 1 wherein the ablation apparatus comprises at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the ablation apparatus to the tissue, the suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening.

20. A system for ablating a tissue comprising:

an ablation apparatus operatively adapted to ablate a first side of the tissue, the ablation apparatus comprising at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the ablation apparatus to the tissue;

a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy being delivered to the first side, the temperature-sensing pad comprising an array of temperature elements in close proximity to each other to effectively detect continuous temperature along the second side of the tissue, and at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;

a suction source in communication with the suction openings, the suction source operatively adapted to provide suction to the suction openings; and

an output device in communication with the pad, the output device operatively adapted to provide a visual display of continuous transmurality of the ablated tissue based on the temperature sensed along the second side of the tissue.

21. A system for assessing transmurality of a linear ablation lesion in a tissue, the system comprising:

an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue to create a linear ablation lesion;

an array of temperature sensors operatively adapted to sense temperature at a plurality of points of contact along a second side of the tissue in response to ablation energy being delivered to the first side of the tissue, the second side of the tissue being opposite the first side of the tissue, wherein the temperature sensors are in close proximity to each other to effectively detect continuous temperature along the second side of the tissue; and

an output device in communication with the array of temperature sensors, the output device operatively adapted to provide an indication of continuous transmurality of the linear ablation lesion at the second side of the tissue based on the sensed temperature.

22. The system of claim 21 wherein the array of temperature sensors forms a grid configuration.

23. The system of claim 22 wherein the output device displays a representation of the grid configuration to indicate where the ablation is both transmural and continuous.

24. The system of claim 23 wherein continuity of the ablation is determined by a substantially continuous pattern of temperature sensors indicating transmurality at the second side of the tissue.

25. The system of claim 21 wherein the output device is adapted to provide an indication of continuity of the linear ablation lesion at the second side of the tissue.

26. The system of claim 21 wherein the indication of transmurality provided by the output device is a visual indication.

27. The system of claim 26 wherein the visual indication is a graphical indication of continuity of the linear ablation lesion at the second side of the tissue.

28. The system of claim 27 wherein the graphical indication includes the use of color.

29. The system of claim 21 wherein transmurality is determined as a function of time and sensed temperature.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE

CONCLUSION

For the above reasons, Appellants respectfully submit that the cited references neither anticipate nor render obvious claims of the pending Application. The pending claims distinguish over the cited references, and therefore, Appellants respectfully submit that the rejections be withdrawn, and respectfully request the Examiner be reversed and claims 1-29 be allowed.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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